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FEB 4 2002

Mailed: February 4, 2002

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,298,520

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,298,520, which claims the human drug product Maxalt® (rizatriptan benzoate) and its method of use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 153 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 153 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 27, 2000 (65 Fed. Reg. 4428). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,734 - 544) + 365 \\ &= 960 \text{ days}\end{aligned}$$

Since the regulatory review period began October 1, 1992, before the patent issue date (March 29, 1994), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 1, 1992 to March 29, 1994 is 544 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (June 29, 1998) when added to the period of extension calculated above (960 days) cannot exceed fourteen years. The period of extension is thus limited to June 29, 2012, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of seventeen years (35 U.S.C. § 154) would expire on January 28, 2012, the period of extension is the number of days to extend the term of the patent from its expiration date to and including June 29, 2012, or 153 days.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 960 days, would extend the patent from January 28, 2012 (35 U.S.C. § 154) to September 14, 2014, which is beyond the 14-year

limit (the approval date is June 29, 1998, thus the 14 year limit is June 29, 2012). The period of extension is thus limited to June 29, 2012, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, January 28, 2012, to and including June 29, 2012, or 153 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,298,520
Granted	:	March 29, 1994
Original Expiration Date	:	January 28, 2012
Applicant	:	Raymond Baker, et al.
Owner of Record	:	MERCK SHARP & DOHME LTD.
Title	:	Triazole Containing Indole Derivatives
Classification	:	514/383
Product Trade Name	:	Maxalt® (rizatriptan benzoate)
Term Extended	:	153 days
Expiration Date of Extension :		June 29, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
P.O. Box 2327
Arlington VA 22202

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. E-mail inquiries should be directed to Karin.Tyson@uspto.gov.


Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read RE: Maxalt® (rizatriptan benzoate)
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 98E-0852
Food and Drug Administration
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